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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,704	03/09/2004	Michael Austin	S63.2-14067-US01	4218
499 7590 05/12/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER EDWARDS, LAURA ESTELLE	
			ART UNIT 1792	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,704

Applicant(s)

AUSTIN ET AL.

Examiner

Laura Edwards

Art Unit

1792

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-29 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-29 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/09 has been entered.

Claim Objections

Claims 17 and 19-21 are objected to because of the following informalities: The status identifiers are incorrect because these claims are not withdrawn.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22/21, 23-26 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423).

Pacetti provides for a system for direct coating of a cylindrically shaped object or stent (22) having a tubular portion with an outer surface, wherein the system comprises a coating material source containing a coating material comprising a solvent and a biologically active material [0063+]; a first roller member (78) having a rotatable surface; and a second roller (76) with a doctor (84) having a surface, wherein the first roller is situated relative to the coating

material source so that the coating material in the coating material source can be transferred to the stent (see Fig. 10 as an example). Pacetti is silent concerning the use of an indirect coating system wherein the second coating roller is situated relative to the first coating roller to transfer coating material from the source to the first coating roller then to the second coating roller to result in coating of the stent. However, it was known in the coating art, at the time the invention was made to provide for an indirect roller coating arrangement to enable a more metered coating of a cylindrically shaped object as evidenced by Shibata (See abstract and Fig. 5). Shibata sets forth a conventional indirect coating apparatus comprising a coating material source (501) containing a desired coating material; a first roller (201) having a surface; and a second roller (301) having a surface, wherein the first roller is situated relative to the coating material source so that the coating material in the coating material source can be transferred to the first roller surface; the first roller and second roller are situated relative to each other so that the first roller can transfer the coating material transferred to the first roller surface to the second roller surface, and the second roller is situated relative to the cylindrical member (32) so that the second roller can transfer the coating material transferred to the second roller surface to the outer surface of the cylindrical member. Thus, it would have been obvious to one of ordinary skill in the art to utilize an indirect coating arrangement as taught by Shibata in place of the Pacetti direct coating arrangement as an alternative arrangement for coating the stent to allow for a more metered supply of coating material onto the surface of the stent thereby enhancing uniformity in coating on the surface of the stent.

With respect to claim 21, while Pacetti does teach a grooved roller surface [0045], Pacetti is silent concerning the use of a transfer roller arrangement wherein the surface of the second

roller is grooved. However, Shibata provides the surface of the second roller (301) being grooved as illustrated in Fig. 4a/b relative to the smooth surface of the first roller (201). In light of the teachings of Shibata, it would have been obvious to one of ordinary skill in the art to utilize in the indirect coating apparatus as defined by the combination above, a second grooved roller in order to control the amount of coating material applied to the stent.

With respect to claim 23, Pacetti does not suggest the surface of the second roller is rougher than the surface of the first roller. Shibata provides for the surface of the second roller (301) being rougher than the surface of the first roller (201) because the surface of the second roller has protrusions thereon as illustrated in Fig. 4a/b relative to the smooth surface of the first roller (201). The surface of the first roller contacts the surface of the second roller and the surface of the second roller contacts the outer surface of the cylindrical member (32). It would have been obvious to one of ordinary skill in the art to utilize in the indirect arrangement a second rougher roller as taught by Shibata to coat the stent with a controlled/minimal amount of coating material.

With respect to claims 25 and 26, Pacetti provides for a single metering doctor (84) but not a supplemental metering mechanism for removing excess coating material. However, Shibata provides for dual metering mechanisms in the form of two blades mechanisms (500/100) for removal of excess coating material from the surface of the first roller (201) so as to control the amount of coating material applied to the cylindrical member. Since dual metering mechanisms are known for use in removing coating from the surface of a single roller applicator, it would have been within the purview of one skilled in the art to utilize any known and

conventional metering mechanisms and combinations thereto to remove excess coating from the surface of the first roller.

With respect to claims 36 and 37, see Pacetti [0067].

Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Pacetti (US 7,175,874).

The combined teachings of Pacetti '544 with Shibata would suggest a coating source in the form of a reservoir. Neither Pacetti '544 nor Shibata suggest two fluid communicating sources (i.e., two tanks or two reservoirs or main tank/sub tank) to act as a supply for coating material. However, it was known in the coating art, at the time the invention was made to provide in a stent coating material supply arrangement, the provision of separate reservoirs/tanks/sources supplied/circulated to a mixing means for subsequent application to the stent so as to allow for control in concentration of ingredients used to coat the stent as evidenced by Pacetti '874 (col. 2, lines 47-52 and col. 3, lines 27-43). It would have been obvious to one of ordinary skill in the art to provide the stent coating material supply arrangement as taught by Pacetti '874 in indirect arrangement as defined by the combination above in order to allow for control of the concentration of ingredients used to form the final composition for application to the stent.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544), Shibata (JP 11-111423), and Pacetti (US 7,175,874) as applied to claim 17 above and further in view of Layrolle et al (US 2001/0008649).

The teachings of Pancetta '544, Shibata, and Pancetta '874 have been mentioned above but none teach or suggest the use of one source or reservoir being a fermentor containing cells. However, it was known in the stent coating art at the time the invention was made, to provide for a source/reservoir to be in the form a fermentor system such as one used for culturing cells so as to be used to coat the stent as evidenced by Layrolle [0037]. In light of the teachings of Layrolle, one of ordinary skill in the art would readily appreciate the inclusion of at least one source having appropriate materials to effect a fermentor as one used in culturing cells to be used to apply such materials to the surface of the stent in the indirect arrangement as defined by the combination above as another option of therapeutic coating material for application to the stent. The inclusion of cells, as a part of a biological coating material, would be within the purview of one skilled in the art.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Kirk Othmer.

The teachings of Pacetti and Shibata have been mentioned above but neither teach or suggest heating/drying the coating on the stent. However, it is well known and conventional in the coating art to use a radiation source (i.e., UV light) to dry or cure an applied coating as evidenced by Kirk Othmer (see page 616, under the heading, "Curing With Ultraviolet,...". In

light of the teachings of Kirk Othmer, one of ordinary skill in the art would readily appreciate the use of an appropriate drying source including UV light, to dry or cure an applied coating to the stent in the indirect coating arrangement as defined by the combination above. It would be within the purview of one skilled in the art to use an appropriate source of energy in the arrangement as defined by the combination above in accordance with the type of coating material applied to the stent.

Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Pomper (US 2,842,092).

The teachings of Pacetti and Shibata have been mentioned above but neither teach or suggest at least one of the first and second roller being adjustable to control the distance between the rollers and thereby control the thickness of coating applied to the stent. However, it is well known and conventional in the coating art to provide at least one adjustable roller (9, 33) provided in a roller pair to control the distance between the two rollers so as to control the thickness of coating supplied on a substrate or article as evidenced by Pomper (col. 3, lines 61-65). It would have been obvious to one of ordinary skill in the art to provide at least one adjustable roller provided in the roller pair (first roller or second roller) in the indirect arrangement as defined by the combination above in order to control the distance between the two rollers so as to control the thickness of coating supplied on the stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

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May 11, 2009